

## HUMAN FACTORS & THE USABILITY OF MEDICAL DEVICES

THE MOST CURRENT, NO-NONSENSE INSTRUCTION FOR NECESSARY TECHNIQUES, ADVANCED CONCEPTS, FDA REVIEW PRIORITIES, COMMON COSTLY MISUNDERSTANDINGS, AND FUTURE DIRECTIONS.

INSTRUCTORS - RONALD D KAYE & DR ROBERT A NORTH

23 thru 25 April 2019 | Minneapolis, MN

### TEN reasons to attend

1. Intensive discussion of FDA perspective, precedents & priorities to ensure successful HF submissions.
2. What the FDA Guidance, **"Applying Human Factors..etc"** says about the HF review process priorities and how this applies to your submission to the FDA.
3. How to interpret and understand, and respond to FDA feedback on pre-submissions including "Type C" meetings, deficiencies and disagreements.
4. HF Testing, test theory and test data, test processes, protocol development and considerations of test bias.
5. Analysis of use-related risks, considerations of IEC-14971 and associated FDA review expectations.
6. "How-to" identify critical user tasks, and develop a Use-related Risk Analysis (URRA) from scratch that will be acceptable upon review and keep prevent unpleasant surprises when your HF submission is reviewed. .
7. Special considerations of review expectations of CDER draft guidance for industry: **"Human Factors Studies & Related Clinical Study ... etc"** AND **"Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA"**
8. Formative testing, theory and practice with a sample medical device with IFU.
9. Group projects beginning with overall HF evaluation plan, identification of users, user groups, user tasks, task criticality, URRA, formative testing, simulated use-based HF/U (Summative) validation testing, data collection, analysis and evaluation of test data, and HF test report.
10. How to avoid vagueness and incompleteness in your submission.



**FDA compliant human factors approaches for achieving safe and effective use of medical devices, medical apps and drug-device combination products. The essential and effective implementation of use-risk analyses, evaluation and design processes.**

**The course offers you the chance to hear directly from the designer of the initial and on-going Human Factors review process at the FDA , and one of the World's leading consultants in HF in Medical Devices.**

**With the experience of over 1000 new device reviews at the FDA and 1000's of industry applications under their belts, you will learn what the assessor is looking for and how to construct your approach and submission strategy to ensure success.**

This course has been revolutionised to include **overall unified theory of use-related risk analysis of device usability, evaluation of user interface design, evaluation and testing including HF/Validation (Summative).**

You will participate in a Summative testing exercise that will

### Day One

- A fresh perspective of the fundamentals of HF submissions, from the FDA reviewers point of view, including
  - Simulated Use
  - Test protocol design.
  - Users, uses and use environments
- Training in your HF/U validation testing; how to avoid "non-representative" training that could invalidate your testing.
- Pre-submission and "Type C" protocol review experiences, and how to evaluate FDA negative feedback; how to evaluate "lack of" specific feedback.
- Discuss use error, use-safety, effectiveness of use, and "residual risk," and their implication for formative testing, HF/U text protocol development, and Reporting
- Considerations for software-based medical devices/medical and mobile medical applications.

### Day Two

- Learn what UI design flaws and design inadequacies are.
- **Group Exercise:** Develop a task analysis, identify and define critical user tasks, develop Use-related Risk Analysis (URRA)
- Learn how to use formative test results to identify and fix UI design problems and fix them prior to HF/U validation testing.
- Learn the three essential kinds of HF/U validation test data and what data is unnecessary for inclusion in your submission.
- Learn the potential applicability and drawbacks of quantitative approaches in HF testing.
- **Group Exercise:** Development of a HF/U validation test protocol for pre-submission review or to use directly in HF/U validation testing.

### Day Three

- **Group Exercise:** Complete and present a summary of HF/U validation Test Report and HF/U Validation Report.
- What makes a FDA review difficult, and what makes it go smoothly
- New developments for HF/U testing, the future of HF for medical devices and the FDA.
- Three most important top ask a potential HF test provider
- Three most important questions to ask your client

feature advanced perspective, understanding in advance key concepts and review priorities; that your test protocol is sound, avoids confusing statements, conclusions, incompleteness and other common reasons for submission rejection. **This exercise can be carried out on one of your own devices, or on a device we will provide.**

You will learn how to ensure a valid and comprehensive evaluation of the test data are included in the report you will submit to the FDA.

This 3-day event will inform you of the Regulatory review expectations of FDA, commonly encountered issues and mistakes. **You will see how reviews are viewed through the eyes of Human Factors Pre-Market Reviewers at FDA.**

We'll discuss the basic foundation for applying human factors, including:

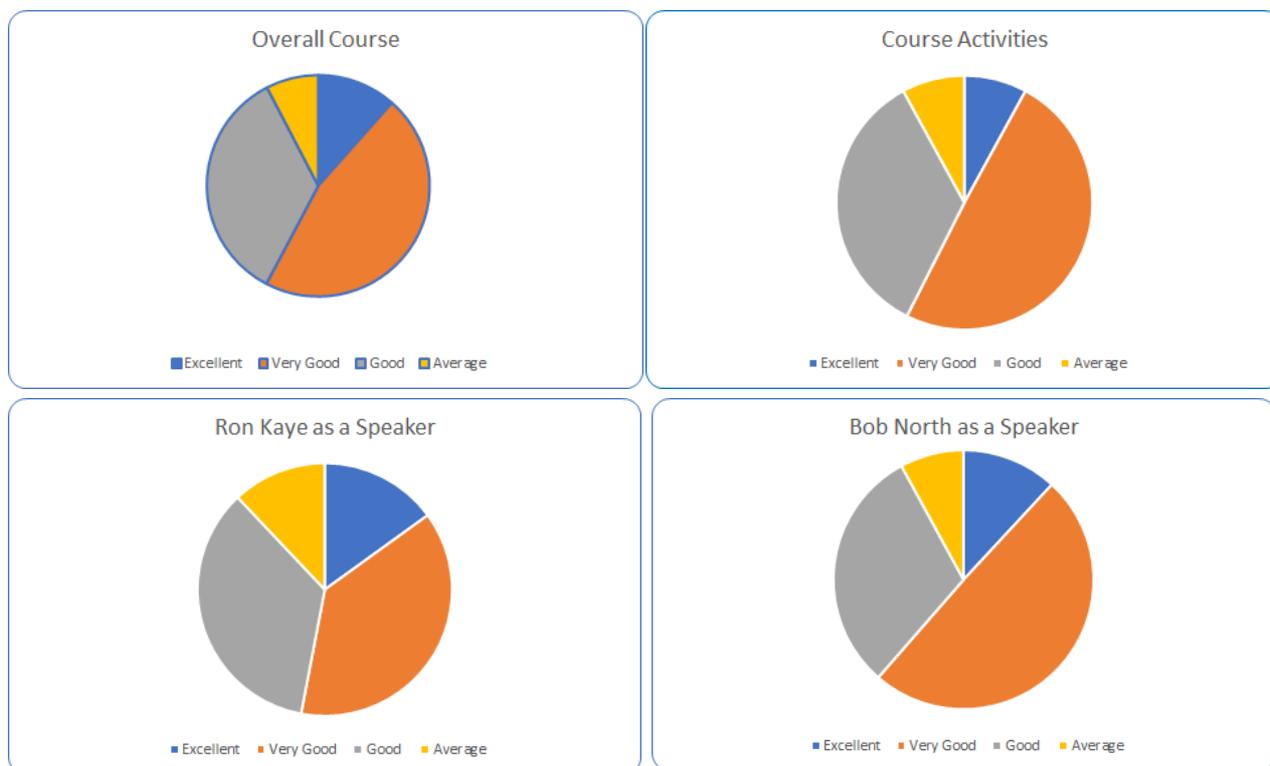
- Critical task identification and development (in class) of a use-related risk analysis (URRA) consistent with FDA expectations for human factors submissions.
- Construction of user groups and test scenarios.
- Considerations for compliance with IEC-62366 and meeting FDA review priorities.
- Discussion of specific HF techniques such as Contextual Inquiry, Heuristic evaluations, Expert Review and Formative testing.
- Class exercise developing a Human Factors/Usability (Summative) test and Test Report consistent with FDA review expectations and priorities will be integrated into the three days of the class including discussion, questions, and critique for each step **(using your own device)**

We'll cover relevant Human Factors standards and their appropriate application to FDA submission materials. There will be group exercises, illustrating the application of Human Factors to medical devices, using methods and language acceptable to FDA HF review teams.

In addition, there will be a faculty Q&A sessions where you can discuss your specific device project related questions (in confidence if necessary)

## Previous Workshop Feedback and Testimonials

This course was held in the UK at the beginning of March and this is a summary of the feedback from the delegates and some of their testimonials.



In the class held in London from 5 to 7 March 2019, delegates scored each area as Excellent to Good, as follows;

Overall Course - 93%

Course Activities - 92%

Ron Kaye as a Speaker - 88%

Bob North as a Speaker - 92%

**"Thank you very much for setting up the course! The three days were extremely informative, enlightening, and entertaining! I feel that I can confidently conduct HF work on our products, and have you to thank for that."** - Human Factors Specialist, Wound Management Corporation (UK/USA))

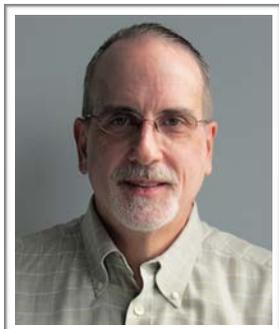
**"Thanks for the course, I learnt a lot about the FDA perspective and enjoyed the Ron-Bob double act alongside the wealth of knowledge"** - Human Factors Manager, Global Drug Delivery Corporation (UK, USA)

**"Many thanks for delivering the course, I thoroughly enjoyed it and certainly learned a great deal"** - Regulatory Director, Hospital Device Corporation (DE, USA)

## Workshop Instructors

**This world class and unique faculty comes together to bring a wealth of knowledge and direct, first-hand FDA experience.**

### *Ronald D Kaye*



Ron Kaye recently retired from the FDA's Center for Devices and Radiological Health where he led the development of its Human Factors initiative during his 19 year tenure at the agency. Ron was the lead author of the original FDA human factors guidance released in 2000, and the current HF guidance released in February 2016, which represents the perspective of the FDA on pre-market submission human factors requirements. During his time at CDRH, Ron participated in over 1000 new device reviews involving human factors work submitted to almost all CDRH divisions, has trained FDA CDRH and CDER HF reviewers and (some) field inspectors, and has participated in Agency post-market responses and recalls associated with use error issues.

Ron has been integrally involved in the education of the FDA and device manufacturers regarding the human factors process in device design and testing. Ron's participation as a faculty member of the AAMI HFE course has brought the FDA human factors message to over 1200 industry practitioners over the past seven years, resulting in a significant improvement in human factors work for new device submissions. He has also been a co-author of the AAMI/ANSI (HE-75) Standard, Human Factors in the Design of Medical Devices and has participated in the international working group that produced IEC 62366, Application of Usability Engineering to Medical Devices.

### *Dr Robert North*



Bob North is Chief Scientist for Human Centered Strategies and an expert on human performance modelling and prediction. Bob is an expert in use error analysis and prediction/ prevention for home and hospital medical devices.

Prior to his consulting career, Bob managed the human factors departments at Medtronic and Honeywell International. Not only is Bob co-author on FDA human factors standard: ANSI/AAMI HE-75 Human Factors Design Guidelines for Medical Devices, but he's also a recognised expert on IEC-60601-1-6 Collateral Standard, Electronic Medical Devices and FDA/CDRH guidance Applying Human Factors and Usability Engineering to Medical Devices. He has served as an adjunct faculty member for short courses (representing the FDA's position) on Design Controls for manufacturers and written over a dozen scholarly articles on Human Factors.

## Event Host

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### *About The Moon on a Stick Ltd*

We are a company based in the UK.

For more information on what we do, and how we could help you, have a conversation with us by calling +44 (0)7535 669017 or writing to [sean@the-moon-on-a-stick.com](mailto:sean@the-moon-on-a-stick.com).

## The Venue

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### *DoubleTree by Hilton Minneapolis - University Area*

DoubleTree by Hilton Minneapolis-University Area is situated east of downtown Minneapolis on the University of Minnesota campus, two blocks from Stadium Village light rail station. Across the street from the University of Minnesota Clinics and Surgery Center, this upscale hotel will excite with contemporary décor and DoubleTree chocolate chip cookie, baked fresh and awaiting your arrival.

The hotel is across the street from the TCF Bank Stadium, home of the Golden Gophers and minutes from the US Bank Stadium, home of the Minnesota Vikings. Watch a game at Target Field, home of the Minnesota Twins or at Target Center, home of the Minnesota Timberwolves. You'll also be close to Fairview Hospital and the Minneapolis Convention Center.

We do not reserve rooms at venue hotels for delegates as we find that using one of the web based hotel pricing sites offers better prices than we can negotiate.

## Course Fee

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The cost of this 3 day course is \$2,200, which will include attendance at all plenary sessions and all course materials. It does not include the cost of travel or accommodation. Discounts are also available for group bookings. Contact us for more information.

## How to make a booking

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On line at: <https://conta.cc/2vz32RF>

By telephoning Sean Warren on +44 (0)7535 669017 - By e-mail to: [sean@the-moon-on-a-stick.com](mailto:sean@the-moon-on-a-stick.com)

## Terms and Conditions

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### *Payment*

Payments must be made before the event takes place. The Moon on a Stick (MOAS) reserves the right to deny access without payment.

### *Cancellation Policy*

Subject to the conditions below, delegates are entitled to a full refund (less administration fee of £75) up to 28 days from the original date of registration. No refunds can be made for cancellations received after this date or for delegates who fail to attend the event. Substitutions are however welcome. In the case of substitutions not being possible, MOAS will offer a credit note, which can be redeemed against future MOAS events for a period of 12 months from the date of cancellation. Where bookings are made less than 28 days prior to the class, only credit notes will be offered should delegates wish to cancel, or not be able to attend.

### *Cancellation of the Event*

In the unlikely scenario of the event being cancelled, either through force majeure or for any other reason, the liability of MOAS will be limited to the full return of the registration fee. No other claims against MOAS will be considered.

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